Proposed Decision Memo for Home Use of Oxygen (CAG-00296N)

Decision Summary

CMS is seeking public comment on our proposed determination that there is sufficient evidence to conclude that the home use of oxygen is reasonable and necessary for Medicare beneficiaries with arterial oxygen partial measurements from 56 to 65 mmHg or whose oxygen saturation is at or above 89% and who therefore do not meet the current requirements for the home use of oxygen as detailed in Section 240.2 of the CMS NCD Manual, only when they are enrolled in an approved clinical trial.

We propose to issue a National Coverage Determination to cover the home use of oxygen for those beneficiaries meeting the qualifications described above who are enrolled subjects in clinical trials identified by CMS and sponsored by the National Heart, Lung & Blood Institute (NHLBI). As a condition of coverage, investigators must adhere to the provisions of HIPAA, the Privacy Act, PRA, and 45 CFR Part 46, if applicable.

We are requesting public comments on this proposed determination pursuant to section 731 of the Medicare Modernization Act. After considering the public comments and any additional evidence we will make a final determination and issue a final decision memorandum.

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Proposed Decision Memo

TO: Administrative File: CAG #00296
Home Use of Oxygen

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SUBJECT: Proposed Decision Memorandum for Home Use of Oxygen
DATE: December 20, 2005

I. Proposed Decision

CMS is seeking public comment on our proposed determination that there is sufficient evidence to conclude that the home use of oxygen is reasonable and necessary for Medicare beneficiaries with arterial oxygen partial measurements from 56 to 65 mmHg or whose oxygen saturation is at or above 89% and who therefore do not meet the current requirements for the home use of oxygen as detailed in Section 240.2 of the CMS NCD Manual, only when they are enrolled in an approved clinical trial.

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We are requesting public comments on this proposed determination pursuant to section 731 of the Medicare Modernization Act. After considering the public comments and any additional evidence we will make a final determination and issue a final decision memorandum.

II. Background

Epidemiology

Chronic obstructive pulmonary disease (COPD) is the most common chronic lung disease in the United States and the most common indication for the use of supplemental oxygen. It is a progressive disorder of the airways that is characterized by a gradual loss of lung function and airflow limitation that is not fully reversible. The symptoms of COPD can range from chronic cough and sputum production to severe shortness of breath. In the U.S., the most important risk factor for the development of COPD is cigarette smoking. COPD is the fourth ranking cause of death in the U.S. and approximately 100,000 people per year die because of the condition.[1] Approximately 12 million adults are diagnosed with the disorder each year.

Persons with COPD also suffer considerable morbidity related to their disease process, including: frequent physician visits or hospitalizations for symptom management, and decline in quality of life secondary to significant difficulty breathing and loss of functional ability.

Disease Process

One of the hallmarks of COPD is the noted abnormalities in the exchange of oxygen and carbon dioxide in the lungs. As a result, patients with COPD suffer from hypoxemia, a condition in which there is inadequate supply of oxygen to blood and tissues. In advanced stages of COPD, hypoxemia worsens to the point where patients require the use of supplemental oxygen therapy to maintain survival.

Interaction of the Intervention with the Disease Process

Criteria have been developed in an attempt to identify those COPD patients who are most likely to benefit from supplemental/long-term oxygen therapy by prolonging survival and preventing further disease related complications such as end organ damage and further reduction in quality of life. It is generally recognized by the medical community that COPD patients with an arterial oxygen partial pressure measurement (PaO_2) $\leq$ 55 mmHg or those with PaO_2 measurements between 56-59 mmHg with evidence of end organ disease (pulmonary hypertension, cor pulmonale, polycythemia, arrhythmias, congestive heart failure, or impaired mental status) benefit from the use of long term oxygen therapy (LTOT).[2,3] These criteria are based largely on two randomized controlled trials performed in 1980 and 1981. However, there is less scientific evidence evaluating the net health outcomes for the subgroup of COPD patients with PaO_2 measurements between 56-65 mmHg receiving LTOT as a therapeutic modality.

III. History of Medicare Coverage

Medicare is a defined benefit program. An item or service must fall within a benefit category as a prerequisite to Medicare coverage. § 1812 (Scope of Part A); § 1832 (Scope of Part B) § 1861(s) (Definition of Medical and Other Health Services). Provided that all coverage requirements are met, Medicare covers home use of oxygen as a supply to durable medical equipment (DME), which is referenced in section 1861(s)(6) of the Social Security Act. Equipment associated with delivering oxygen such as oxygen concentrators, portable, and stationary oxygen systems qualify as DME, while the oxygen contents serve as the DME supply. Thus, the home use of oxygen falls within the DME benefit category.

Medicare has a National Coverage Determination on Home Use of Oxygen (Rev. 1, 10-03-03) at Section 240.2 of the National Coverage Determinations Manual.

IV. Timeline of Recent Activities

August 16, 2005	CMS opened an internally generated National Coverage Determination (NCD) reconsideration to determine if there is sufficient evidence to change the current policy for beneficiaries having arterial oxygen partial pressure measurements in the range 56-65 mmHg.
	The initial 30-day public comment period began.
September 16, 2005	End of public comment period.

V. FDA Status

Oxygen itself is a naturally occurring element, readily available commercially from a variety of industrial and other sources. While the FDA regulates the equipment and delivery systems required for providing oxygen therapy, it does not regulate the use of oxygen.

VI. General Methodological Principles

When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service falling within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve net health outcomes for patients. Improved net health outcomes is one of several considerations in determining whether an item or service is reasonable and necessary. In general, features of clinical studies that improve quality and decrease bias include the selection of a clinically relevant cohort, the consistent use of a single good reference standard, and the blinding of readers of the index test, and reference test results.

A detailed account of the methodological principles of study design that agency staff utilizes to assess the relevant literature on a therapeutic or diagnostic item or service for specific conditions can be found in Appendix B.

VII. Evidence

A. Introduction

We are providing a summary of the evidence we considered during our review. We will, of course, consider additional evidence submitted through the public comment period. The evidence reviewed to date in this proposed NCD includes the published medical literature on pertinent clinical trials of home oxygen.

B. Discussion of evidence reviewed

1. Question

Is the quality of evidence adequate to conclude that the home use of oxygen can improve net health outcomes and is reasonable and necessary for Medicare beneficiaries who have arterial oxygen partial pressure measurements from 56 mmHg to 65 mmHg or whose oxygen saturation is at or above 89%?

2. External technology assessments

In 2004, CMS requested an external technology assessment (TA) from the Agency for Healthcare Research and Quality (AHRQ) in order to summarize the available clinical and scientific evidence on the appropriateness and effective use of LTOT in patients with COPD.[4] The TA authors concluded that there is insufficient scientific evidence to assess the survival benefit of patients with COPD and PaO_2 measurements in the range of 56-65 mmHg. This conclusion is based on the lack of scientifically rigorous evidence used to guide the use of LTOT in COPD patients. In addition, the majority of studies reviewed by the TA authors reported findings for the subgroup of patients with severe resting hypoxemia or moderate hypoxemia with certain advanced manifestation of disease such as concomitant cardiac impairment. Inconsistencies in identifying or reporting evidence regarding non-mortality outcomes such as rates of hospitalization, improvement in lung physiology, and quality of life measures were also noted by the TA authorities. This information was subsequently presented as part of an expert working group convened by NHLBI to discuss LTOT in May of 2004.[5] The NHLBI report cited the efficacy of LTOT in patients with moderate resting hypoxemia as an important future research initiative. Hours of oxygen utilization, therapeutic benefits independent of survival, and the identification of specific population subgroups such as those with pulmonary hypertension or low BMI were identified as important to informing the current body of evidence regarding COPD patients and LTOT as a therapeutic modality.

3. Internal technology assessments

Systematic reviews are based on a comprehensive search of published studies to answer a clearly defined and specific set of clinical questions. A well-defined strategy or protocol (established before the results of the individual studies are known) guides this literature search. Thus, the process of identifying studies for potential inclusion and sources for finding such articles is explicitly documented at the start of the review. Finally, systematic reviews provide a detailed assessment of the studies included.

Literature search methods

A search of the MEDLINE database, The Cochrane Library, the National Guidelines Clearinghouse, and the International Network of Agencies for Health Technologies Assessment (INAHTA) database and a hand search of bibliographies included in the articles were conducted. The internal TA searched for and evaluated literature addressing the subgroup of patients with COPD with PaO_2 in the range of 56-65 mmHg receiving LTOT as the major treatment modality. Filters and limitations were used, and inclusion and exclusion criteria were developed to identify the appropriate articles to be reviewed.

Evidence Review

A paucity of scientific evidence currently exists to objectively evaluate the net health outcomes of long term oxygen therapy for hypoxemic patients with arterial oxygen partial pressure measurements (PaO_2) in the range of 56-65mmHg.

Sliwiński (1992) performed a prospective cohort study of 46 patients with COPD in order to determine the acute effect of oxygen on pulmonary artery pressure (PAP). Participants were divided into two groups, those with $PaO_2 \leq 55$ mmHg or PaO_2 56-65 mmHg if accompanied by radiologic signs of pulmonary hypertension, ECG signs of right ventricular hypertrophy, or elevated hematocrit. They were further classified as responders and non-responders based on changes in PAP in relation to treatment with oxygen. The number or percentage of patients in each group was not reported and results were not categorized by group. The average use of oxygen was reported as 14.6h/day. Outcome measures of interest included survival and hospitalizations related to COPD exacerbations. The two year survival rate was 69% in non-responders and 57% in responders. On average there were 1.4 versus 0.8 hospital admissions when comparing non-responders and responders.

Sandek (2001) performed a prospective cohort study of 14 patients with COPD and PaO_2 measurements in the range of 56-59 mmHg to determine the effect of LTOT on pulmonary function and other physiological measurements. No significant changes were noted. The author concluded that six months of LTOT in stable COPD patients does not correlate to clinically important changes in pulmonary physiology.

Gorecka (1997) performed a randomized clinical trial of 135 COPD patients with PaO_2 measurements in the range of 56-65 mmHg. Patients were randomized to conventional therapy with or without LTOT. Outcome measures of interest included survival, hours of oxygen use, and survival predictors. There was no significant difference in survival in the control and treatment arms of the trial. In addition, oxygen use greater than 15 hours per day did not improve survival. Younger age, spirometric values, and higher BMI were predictors of survival. The cumulative survival rates at one, two, and three years were 88%, 77%, and 66%.

Hjalmarsen (1999) completed a retrospective study of 124 patients with COPD. Patients were divided into two groups based on PaO_2 measurements: Group I $PaO_2 \geq 55$ mmHg and Group II $PaO_2 \geq 56$ mmHg with coexisting polycythemia or cor pulmonale. The major outcome of interest was survival. The authors concluded that survival was similar for both patient groups at the same level of loss of lung function.

An additional randomized control trial study by Chaouat (1999) evaluated COPD patients with PaO_2 measurements in the range of 60-64 mmHg. However, patients only received oxygen therapy at night. Authors noted no significant difference in mortality between the treated and control groups based on an intention to treat analysis.

4. MCAC

A Medicare Coverage Advisory Committee (MCAC) meeting was not convened on this issue.

5. Evidence-based guidelines

Institute for Clinical Systems Improvement (ICSI). Chronic obstructive pulmonary disease. Bloomington (MN): 2004 Dec.

The guidelines note that LTOT improves survival and quality of life in hypoxemic patients and should be used as supplemental therapy for patients with resting $PaO_2 \leq 55$ mmHg. No specific guidance was given for patients with PaO_2 measurements in the range of 56-65 mmHg.

Chronic obstructive pulmonary disease. National clinical guideline on management of chronic obstructive pulmonary disease in adults in primary and secondary care. Thorax 2004 Feb; 59 suppl 1:1-232.

The guideline notes that clinicians should be aware that inappropriate oxygen therapy in COPD patients may cause respiratory depression. LTOT is indicated based on current Medicare guidelines. LTOT must be administered for at least 15 hours per day and great benefits are seen with use 20 hours per day.

Global Initiative for Obstructive Lung Disease(GOLD),World Health Organization (WHO), NHLBI. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. Bethesda (MD). 2004.

This guideline is an update to previous guidelines. Major points include a discussion regarding the lack of proven benefit for supplemental oxygen provided before, during, or after exercise and the ongoing consensus that administration of LTOT for patients with severe hypoxemia has been shown to increase survival.

6. Professional Society Position Statements

Adult domiciliary oxygen therapy. Position statement of the Thoracic Society of Australia and New Zealand. 2005.

The position paper notes that patients with COPD and stable daytime PaO_2 of $\leq$ 55 mmHg live longer and have a better quality of life if provided with LTOT.

7. Expert Opinion

Apart from the public comments discussed below, we have not currently received any expert opinions on the home use of oxygen for beneficiaries who do not meet the requirements of Section 240.2 of the CMS NCD Manual.

8. Public Comments

Initial public comments

CMS utilizes the initial public comments to inform its proposed decision. We will respond in detail to the final public comments on this proposed decision.

During the initial public comment period, CMS received written statements from three respiratory therapists, five associations, two physicians and six individuals (many of whom work in the health care field). The comments are summarized below.

- CMS should increase coverage to include beneficiaries having oxygen partial pressure measurements in the range of 56-65 mmHg.
- Coverage of oxygen for beneficiaries having oxygen partial pressure measurements in the range of 56-65 mmHg could reduce costs in other expenditures, such as hospital and emergency room visits.
- CMS should consider covering oxygen for those patients in a nursing home.
- CMS should reconsider the criteria and reimbursement for Independent Testing Facilities.
- Medi-Cal and Medicaid usually apply the same policy as Medicare so this would help those patients as well.
- CMS should maintain the coverage for group II patients until randomized controlled studies are available to contradict from NOTT and BMRC.
- It may be beneficial to expand coverage to a subset of group II patients to include PaO2 levels up to 65 mmHg.
- The subset of patients in group II should be retested/recertified for continuing use of oxygen so long as the payment policy allows physicians to bill for such retesting.

- CMS should consider guidance by NIH and other research bodies in the May 10-11, 2004 LTOT in COPD working group executive summary.
- One commenter suggested that the specific statutory provision in 42 U.S.C. section 1395m(a)(5)(E) barred CMS from changing the current qualification criteria for home oxygen. Currently the statute specifies that beneficiaries must have an initial arterial blood gas value at or above a partial pressure of 56 or an arterial oxygen saturation at or above 89 percent. We disagree with the commenter. In fact, 42 U.S.C. § 1395m(a)(5) expressly authorizes the agency to alter the standards by providing "or such other values, pressures, or criteria as the Secretary may specify [.] In light of this express delegation, it is clearly within the agency's authority to consider changing the arterial blood gas value or the arterial saturation levels when necessary.

VIII. CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act § 1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage.

Question:

Is the quality of evidence adequate to conclude that the home use of oxygen can improve net health outcomes and is reasonable and necessary for Medicare beneficiaries who have arterial oxygen partial pressure measurements from 56 mm Hg to 65 mm Hg or whose oxygen saturation is at or above 89%?

The evidence reviewed is inconclusive whether or not the use of LTOT improves net health outcomes in persons who have $PaO_2 \geq 56$ mmHg. The generalizability to the Medicare population at large of the conclusions drawn from the reviewed trials is limited by small sample sizes and study protocols' focus on particular subsets of LTOT. We believe that important questions regarding the optimal daily use and long-term duration of LTOT for this subset of patients are not completely answered by the available data.

A sufficient inference of benefit can be drawn to support limited coverage in the context of an NHLBI-sponsored clinical trial. We further believe that NHLBI-sponsored clinical trials offer safeguards for patients to ensure appropriate patient evaluation and selection and reasonable use of home oxygen. We propose that coverage for the use of home oxygen in NHLBI-sponsored clinical trials could provide clinical benefits to Medicare beneficiaries with chronic heart and lung disease, and that the infrastructure to provide those benefits is integral to a clinical trial. Such a clinical trial will assure informed individualized analysis and evaluation of the response to oxygen and patient health status, as well as an adequate plan for data and safety monitoring.

IX. Proposed Conclusion

CMS is seeking public comment on our proposed determination that there is sufficient evidence to conclude that the home use of oxygen is reasonable and necessary for Medicare beneficiaries with arterial oxygen partial measurements from 56 to 65 mmHg or whose oxygen saturation is at or above 89% and who therefore do not meet the current requirements for the home use of oxygen as detailed in Section 240.2 of the CMS NCD Manual, only when they are enrolled in an approved clinical trial.

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APPENDIX A [PDF, 69KB]

APPENDIX B

General Methodological Principles of Study Design
(Section VI of the Decision Memorandum)

When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service is reasonable and necessary. The overall objective for the critical appraisal of the evidence is to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve net health outcomes for patients.

We divide the assessment of clinical evidence into three stages: 1) the quality of the individual studies; 2) the generalizability of findings from individual studies to the Medicare population; and 3) overarching conclusions that can be drawn from the body of the evidence on the direction and magnitude of the intervention's potential risks and benefits.

The methodological principles described below represent a broad discussion of the issues we consider when reviewing clinical evidence. However, it should be noted that each coverage determination has its unique methodological aspects.

Assessing Individual Studies

Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Strength of evidence generally refers to: 1) the scientific validity underlying study findings regarding causal relationships between health care interventions and health outcomes; and 2) the reduction of bias. In general, some of the methodological attributes associated with stronger evidence include those listed below:

- Use of randomization (allocation of patients to either intervention or control group) in order to minimize bias.
- Use of contemporaneous control groups (rather than historical controls) in order to ensure comparability between the intervention and control groups.
- Prospective (rather than retrospective) studies to ensure a more thorough and systematical assessment of factors related to outcomes.
- Larger sample sizes in studies to demonstrate both statistically significant as well as clinically significant outcomes that can be extrapolated to the Medicare population. Sample size should be large enough to make chance an unlikely explanation for what was found.
- Masking (blinding) to ensure patients and investigators do not know to which group patients were assigned (intervention or control). This is important especially in subjective outcomes, such as pain or quality of life, where enthusiasm and psychological factors may lead to an improved perceived outcome by either the patient or assessor.

Regardless of whether the design of a study is a randomized controlled trial, a non-randomized controlled trial, a cohort study or a case-control study, the primary criterion for methodological strength or quality is the extent to which differences between intervention and control groups can be attributed to the intervention studied. This is known as internal validity. Various types of bias can undermine internal validity. These include:

- Different characteristics between patients participating and those theoretically eligible for study but not participating (selection bias).
- Co-interventions or provision of care apart from the intervention under evaluation (performance bias).
- Differential assessment of outcome (detection bias).
- Occurrence and reporting of patients who do not complete the study (attrition bias).

In principle, rankings of research design have been based on the ability of each study design category to minimize these biases. A randomized controlled trial minimizes systematic bias (in theory) by selecting a sample of participants from a particular population and allocating them randomly to the intervention and control groups. Thus, in general, randomized controlled studies have been typically assigned the greatest strength, followed by non-randomized clinical trials and controlled observational studies. The design, conduct and analysis of trials are important factors as well. For example, a well designed and conducted observational study with a large sample size may provide stronger evidence than a poorly designed and conducted randomized controlled trial with a small sample size. The following is a representative list of study designs (some of which have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

- Randomized controlled trials
- Non-randomized controlled trials
- Prospective cohort studies
- Retrospective case control studies
- Cross-sectional studies
- Surveillance studies (e.g., using registries or surveys)
- Consecutive case series
- Single case reports

When there are merely associations but not causal relationships between a study's variables and outcomes, it is important not to draw causal inferences. Confounding refers to independent variables that systematically vary with the causal variable. This distorts measurement of the outcome of interest because its effect size is mixed with the effects of other extraneous factors. For observational, and in some cases randomized controlled trials, the method in which confounding factors are handled (either through stratification or appropriate statistical modeling) are of particular concern. For example, in order to interpret and generalize conclusions to our population of Medicare patients, it may be necessary for studies to match or stratify their intervention and control groups by patient age or co-morbidities.

Methodological strength is, therefore, a multidimensional concept that relates to the design, implementation and analysis of a clinical study. In addition, thorough documentation of the conduct of the research, particularly study selection criteria, rate of attrition and process for data collection, is essential for CMS to adequately assess and consider the evidence.

Generalizability of Clinical Evidence to the Medicare Population

The applicability of the results of a study to other populations, settings, treatment regimens and outcomes assessed is known as external validity. Even well-designed and well-conducted trials may not supply the evidence needed if the results of a study are not applicable to the Medicare population. Evidence that provides accurate information about a population or setting not well represented in the Medicare program would be considered but would suffer from limited generalizability.

The extent to which the results of a trial are applicable to other circumstances is often a matter of judgment that depends on specific study characteristics, primarily the patient population studied (age, sex, severity of disease and presence of co-morbidities) and the care setting (primary to tertiary level of care, as well as the experience and specialization of the care provider). Additional relevant variables are treatment regimens (dosage, timing and route of administration), co-interventions or concomitant therapies, and type of outcome and length of follow-up.

The level of care and the experience of the providers in the study are other crucial elements in assessing a study's external validity. Trial participants in an academic medical center may receive more or different attention than is typically available in non-tertiary settings. For example, an investigator's lengthy and detailed explanations of the potential benefits of the intervention and/or the use of new equipment provided to the academic center by the study sponsor may raise doubts about the applicability of study findings to community practice.

Given the evidence available in the research literature, some degree of generalization about an intervention's potential benefits and harms is invariably required in making coverage determinations for the Medicare population. Conditions that assist us in making reasonable generalizations are biologic plausibility, similarities between the populations studied and Medicare patients (age, sex, ethnicity and clinical presentation) and similarities of the intervention studied to those that would be routinely available in community practice.

A study's selected outcomes are an important consideration in generalizing available clinical evidence to Medicare coverage determinations. One of the goals of our determination process is to assess net health outcomes. These outcomes include resultant risks and benefits such as increased or decreased morbidity and mortality. In order to make this determination, it is often necessary to evaluate whether the strength of the evidence is adequate to draw conclusions about the direction and magnitude of each individual outcome relevant to the intervention under study. In addition, it is important that an intervention's benefits are clinically significant and durable, rather than marginal or short-lived. Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits.

If key health outcomes have not been studied or the direction of clinical effect is inconclusive, we may also evaluate the strength and adequacy of indirect evidence linking intermediate or surrogate outcomes to our outcomes of interest.

Assessing the Relative Magnitude of Risks and Benefits

An intervention is not reasonable and necessary if its risks outweigh its benefits. Net health outcomes is one of several considerations in determining whether an item or service is reasonable and necessary. CMS places greater emphasis on health outcomes actually experienced by patients, such as quality of life, functional status, duration of disability, morbidity and mortality, and less emphasis on outcomes that patients do not directly experience, such as intermediate outcomes, surrogate outcomes, and laboratory or radiographic responses. The direction, magnitude, and consistency of the risks and benefits across studies are also important considerations. Based on the analysis of the strength of the evidence, CMS assesses the relative magnitude of an intervention or technology's benefits and risk of harm to Medicare beneficiaries.

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[1] NHLBI Data Fact Sheet. Chronic Obstructive Pulmonary Disease. Publication No. 03-5229; March 2003.

[2] Continuous or nocturnal oxygen therapy in hypoxemic chronic obstructive lung disease: a clinical trial. Nocturnal Oxygen Therapy Trial Group. Ann Intern Med 1980;93:391-8.

[3] Long term domiciliary oxygen therapy in chronic hypoxic cor pulmonale complicating chronic bronchitis and emphysema. Report of the Medical Research Council Working Party. Lancet 1981; 1(8222): 681-6.

[4] Lau J, Chew P, Wang C, White A. Long-Term Oxygen Therapy for Severe COPD. June 2004 Prepared for AHRQ by Tufts-New England Medical Center EPC.

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